**Remarks**

Claims 8-14 are pending in the current application. A declaration of inventor Dr. Yaakov Naparstek is submitted under Rule 1.132 in connection with this response.

**Rejections under 35 U.S.C. §103**

Claims 8-14 are rejected under 35 U.S.C.§103(a) as being unpatentable over Gaubitz et al. (1993) in view of U.S. 6,228,363 and Madaio et al. (1996). Applicants respectfully traverse this rejection in view of following remarks and the data presented in the declaration.

At the outset, Applicant would like to point out that none of the references cited disclose successful therapeutic treatment with extracorporeal removal of specific antibodies. Gaubitz et al. is cited for disclosure of plasmaphoresis to remove all antibodies from the plasma of a lupus (SLE) patient, and the '363 patent discloses that the R38 protein can be administered to a patient to bind lupus antibodies. Madiao et al. is redundant, and was apparently cited to show that antibodies from lupus patients recognize laminin, a cell protein from which R38 is derived, but this was already recognized in the '363 patent.

The Examiner asserts that it is obvious to use the R38 protein in methods of extracorporeal treatment of a patient's plasma to remove lupus antibodies, and it is implied that somehow the methods of the present invention would be expected to be therapeutically successful. Applicant disagrees with this assertion and implication.

As explained previously, there is no guarantee that the same binding shown on an ELISA plate will occur in a column, due to conformational changes in the protein when attached to a substrate. In fact, Applicant submits that binding is not at all expected, due to this difference.

Additionally, therapeutic success is also not necessarily expected, because of the time constraints on binding due to passing plasma through a column. The combination of these hurdles is significant, and non-specific removal of all antibodies in a column is not predictive of the success of removal of specific antibodies. The fact that the invention works is not expected, based on the teachings of Gaubitz et al. in combination with the '363 patent or Madaio et al.

As set forth in the attached Sec. 132 declaration, Applicant treated a patient having systemic lupus erythematosus (SLE) using the methods of the present invention, namely, extracorporeal removal of lupus antibodies. Plasma levels of lupus antibodies were measured before and immediately after treatment, and then at several time periods (weeks) after treatment. A graph of the clinical result is presented in the declaration. The data indicate that lupus antibody levels continued to decline beyond the levels observed immediately post treatment, for a period of time (up to five weeks) before an increase was again noted. The continuing decline in antibody levels is indeed an unusual and unexpected result, one that could not have been predicted from the disclosure of any of the references cited, nor any reference known to Applicant. Applicant respectfully submits that any alleged *prima facie* case of obviousness has been overcome with evidence of unexpected results.

The Examiner asserts in the Final Rejection of September 8, 2006 that evidence of unexpected results must "properly appear in the specification" and can therefore be disregarded if not in the application as filed. Applicant submits that this is an incorrect application of the law and requests citation to the appropriate authority. As far as Applicant is aware, evidence of unexpected results may submitted in a declaration filed under Rule 1.132 during prosecution, as set forth in the MPEP Section 716. An entire section of the MPEP is devoted to this subject (declarations under 1.132). MPEP 716.01 states that "Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted prior to a final rejection" and in several other circumstances. Accordingly, the Examiner is obligated to consider evidence of unexpected results submitted during prosecution, where the evidence is submitted to support the arguments being made.

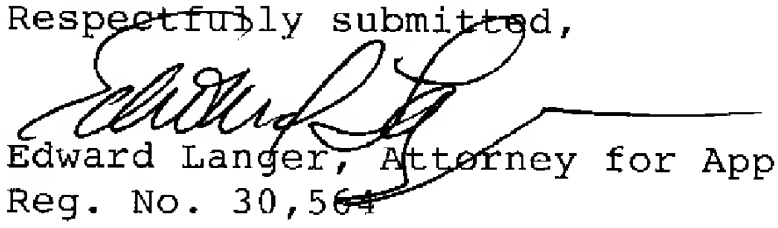
It is further asserted by the Examiner in the Office Action dated January 30, 2006 that submission of evidence of unexpected results is "an admission that the invention is indeed obvious but patentable in view of the unexpected results". This assertion is also an incorrect application or understanding of the law. Citation to the appropriate authority is again requested. Applicant has made no such admission in any statement, nor by the submission of evidence of unexpected results. Applicant submits that the evidence of unexpected results establishes that the present invention is non-obvious and fully patentable in view of

the references cited. Withdrawal of the §103 rejection is respectfully requested.

**Conclusion**

Applicant submits that all outstanding issues have been addressed and that Claims 8-14 are in condition for allowance; such action is respectfully requested at an early date.

Respectfully submitted,



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